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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| CRANE, LAWRENCE E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/740,075 | RENSHAW ET AL. | |
| | Examiner | Art Unit | |
| | L. E. Crane | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *March 13, 2006 (amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,5 and 7-30* is/are pending in the application.

4a) Of the above claim(s) *30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 7-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/6/04;2/14 etc.*. (5 documents)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **4 and 6** have been cancelled, claims **1, 3, 5, 7, 12, and 14-18** have been amended, the disclosure has not been amended, and new claims **21-30** have been added as per the amendments filed March 13, 2006. Four Information Disclosure Statements (4 IDSs) filed December 6, 2004, February 14, 2005, June 20, 2005 and June 27, 2005 has been received with all cited references and made of record unless otherwise noted on the copies of said IDS's returned to applicant.

Claims **1-3, 5 and 7-30** remain in the case.

Newly submitted claim **30** directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the subject matter of the noted claim is directed to subject matter which is beyond the scope of the originally filed and searched claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim **30** withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and MPEP §821.03.

Claims **1-3, 5 and 7-29** remain under examination.

Note to applicant: when a rejection or objection refers to a claim **X** at line y, the line number is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-3, 5 and 7-29** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed enabling exemplifications.

Examiner has inspected the disclosure and Figures 1 and 2, and finds therein what appears to be data concerning the reactions to the administration of CDP-choline by a single human host, apparently a 33 year old subject who appears to be addicted to or habituated to, alcohol, cocaine and tobacco and who consumes caffeinated beverages, a possible additional

habituation. Applicant has claimed broadly the treatment of sleep deprivation in all human and mammalian hosts, but has not provided sufficient exemplifying data to support such a broad scope of subject matter. Examiner suggests that applicant needs to establish individually the effective treatment of specific sleep related disease conditions (insomnia, narcolepsy, etc. etc.) by testing appropriate groups of subjects (night shift workers, interns doing 24 hour stints, etc.). Alternatively examiner suggests applicant may elect to demonstrate the effective treatment of specific-drug addicted hosts who suffer from sleep deprivation(s). In any event the instant data set is simply inadequate to support the instant patent claims because of the lack of showing that the claimed effects of CDP-choline administration are common to a reasonable number of similarly situated hosts in need of such treatment.

Because applicant has provided some data, applicant may elect to supply additional data using a declaration under 37 C.F.R. §1.132. Alternatively applicant's counsel may advise applicant concerning other strategies for maintaining the instant subject matter under prosecution until such time that sufficient data has been supplied to adequately support grant of a patent claim or claims.

Claims **1-3, 5 and 7-29** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: the breadth of many of the claims is excessive because of the presence of generic terms including "treating a sleep disorder," and "increasing cognitive function."

B. The nature of the invention: the invention is directed to treatment of sleep disorders including those disorders caused by drug addictions.

C. The state of the prior art: the administration of CDP-choline is associated in some prior art references with the effective amelioration of insomnia, particularly in elderly hosts. See the prior art-based rejections below.

D. The level of one or ordinary skill: the level of the ordinary practitioner is variable, because the administration of CDP-choline is known to be effective in some hosts, but the remainder of the claimed active ingredients have not been shown herein to have similar activities.

E. The level of predictability in the art: the art of treating sleep disorders is highly variable in its predictability because of the large array of different causes or circumstances under which it is observed to occur, both known (drugs, shift work, etc.) and unknown (aging, physical injury, etc.).

F. The amount of direction provided by the inventor: referring to Figures 1 and 2, it appears that applicant has only tested the administration of CDP-choline on a single human host who is apparently afflicted with multiple chemical dependencies including to alcohol, cocaine and caffeine.

G. The existence of working examples: there appears to be only a single working example and no clear indication decernable by examiner concerning what particular sleep disorder or disorders where being treated in this particular host.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive in light of the indefiniteness and functionality of the claims and because the exemplary evidence is so limited in quantity, and consequently the minimum necessary guidance concerning various different active ingredients and their application to various different sleep disorder treatments, is simply absent.

Claims **1-2, 12-15, 17, 19, 22, 27 and 28** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at lines 3-4, the presence of numerous acronym abbreviations is noted and renders the claim incomplete. Applicant is respectfully requested to insert the complete

chemical name followed by the abbreviation at the first occurrence in the claims; e.g. -- cytidine monophosphate (CMP) --, etc. All subsequent occurrences of the same compound in later claims and presently represented by the same abbreviation need not be modified. See also claims **12, 17 and 22** wherein newly added abbreviations may be present.

In claim **1** at line 3 the term "compound comprising" is indefinite because the subsequent list of compounds are all named as separate compounds rather than substituent moieties of a larger molecular species, and because the larger molecular species implied by the term "comprising" (including) is not subsequently defined thereby leaving the metes and bounds of the claimed subject matter incomplete. See also claims **12, 15, 17 and 22** wherein the same problem reoccurs.

In claim **1** at lines 7-8, the entire phrase beginning with ", thereby" is superfluous as a repetition of the preamble and should be deleted in its entirety. See also the last phrase in claim **27**.

In claim **2** at lines 2-3, the term "improves the sleep quality of said mammal during the day" is misleading. Did applicant intend the term to read -- improves the sleep quality of said mammal when sleeping is required during the day --? Additional improvement of the noted claim's clarity of meaning may be realized by inserting the term -- daytime -- before the terms "fatigue" and "wakefulness." See also claim **28**.

In claim **12** at line 1, the term "a sleep disorder" is generic and therefore renders the instant claim indefinite. Applicant is respectfully requested to specify all of the particular sleep disorder or disorders to be treated.

In claim **12** at lines 4-5, the term "is not compromised by an existing physical condition" is an improper negative limitation because the particular "existing physical limitation[s]" have not been specified in the claim.

In claim **13** the term "said sleep disorder is caused by a substance abuse disorder" lacks proper antecedent basis. Examiner suggests introduction of the term -- further comprising -- in order to effectively address this expansion of the subject matter definition of claim **12**. Said term also renders the claim incomplete because the particular "substance abuse disorder" has not been specified. See also claim **23** in re its dependence from claim **22**.

Claim **14** is incomplete because the list of abused substances is not preceded by the term -- caused by --. See also claim **24**.

In claim **17** at line 9, the term "thereby increasing the cognitive functioning of said mammal" is superfluous as a repetition of the preamble and should be deleted in its entirety.

In claim **19** the term "not caused by a substance abuse disorder" renders the claim incomplete because the particular substance abuse disorder(s) has(have) not been specified.

In claim **22** at line 6, the term "wherein said sleep disorder is not insomnia or sleep apnea" is an improper negative limitation because the generic preamble term "a sleep disorder" is not specifically defined in terms of what sleep disorder or disorders are to be treated.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-3, 5 and 7-29** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-16*** of U. S. Patent No. **6,103,703** (PTO-1449 ref. **A10**). Although the conflicting claims are not identical, they are not patentably distinct from each other because claimed the methods of treatment, "increasing cognitive functions in a sleep deprived mammal, treatment of insomnia, or other cognitive dysfunction"

versus "preventing or ameliorating a stimulant induced disorder," and wherein the alleged active ingredients are selected from a cytidine- or a 2'-deoxycytidine-5'-nucleotide, are directed to substantially overlapping subject matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

Claims **1-3, 5 and 7-29** are rejected under 35 U.S.C. §102(**b**) as being anticipated by **Yamamoto et al. '486** (PTO-892 ref. **A**).

Applicant is referred to the **'486** patent at columns 3, line 30 through column 4 line. See in particular reference to sleep inducing substances at column 3, lines 31-36, including uridine and adenosine. See also column 4, lines 4-23, wherein compounds including "cytidine" are disclosed to be effective in the inhibition of sleep. Therefore, in light of the claims in the **'486** patent wherein "regulating a rhythm of sleep" is found at column 8 in the preamble of claim *1*, the instant claims wherein regulation of the sleep/wake cycle is deemed to have been anticipated. In addition, in light of the teaching of inhibition of sleep for compounds including cytidine, it is presumed that administration of cytidine will enhance cognitive functions in a mammal and therefore effectively include claims directed to this function as well. And lastly, since the **'486** patent includes both sleep inducing and sleep inhibiting substances, it is inherent

that administering these compounds in proper sequence will effectively treat a sleep disorder as required by instant claim **12**.

Claims **1-3, 5, 7-14, 16-21 and 27-29** are rejected under 35 U.S.C. §102 (**b**) as being anticipated by **Fernandez** (PTO-1449 ref. **C47**).

Applicant is referred to page 1073 of the cited reference at column 1, lines 11-17 of the "Summary," and particularly to line 15 wherein the administration of CDP-choline to treat insomnia is specifically taught. See also page 1076, column 2, next to last line and associated explanatory text.

Claims **1-3, 5 and 7-29** are rejected under 35 U.S.C. §102 (**e**) as being anticipated by **Wurtman et al. '415** (PTO-1449 ref. **A15**).

Applicant is referred to the **'415** reference at paragraph 0025, at paragraphs 0052-0057, and claims ***7 and 8-11*** wherein the administration of citicoline (CDP-choline) is disclosed to effectively treat cognitive dysfunctions including insomnia, motor coordination, and memory impairment.

Claims **1-3, 5, 7-14 and 16-29** are rejected under 35 U.S.C. §102 (**e**) as being anticipated by **Ferrer International '288** (PTO-1449 ref. **B9**).

Applicant is referred to page 5 wherein the administration of pharmaceutical compositions including CDP-choline are disclosed to effectively treat a variety of symptoms related to alcoholism and withdrawal therefrom including insomnia and disorientation.

Claims **1-3, 5, 7-14 and 16-29** are rejected under 35 U.S.C. §102 (**b**) as being anticipated by **Radulovacki et al.** (PTO-1449 ref. **C31**).

Applicant is referred to page 268, column 1, wherein reference is made to prior art wherein " ... some experimental evidence suggests that adenosine may have a role in sleep."

See also **Satoh et al** (PTO-1449 ref. **C35**) at page 155, column 2 wherein a similar disclosure has been made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

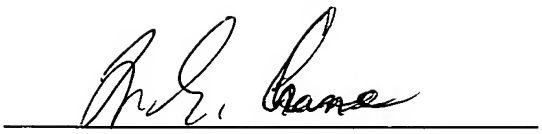
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
**04/21/2006**



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